Bimekizumab Long-Term Efficacy and Safety in Patients with Psoriatic Arthritis with Baseline Plaque Psoriasis/Nail Involvement to 3 Years

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Objective

To report the 3-year efficacy and safety of bimekizumab (BKZ) in patients with active psoriatic arthritis (PsA) with plaque-type psoriasis (psoriasis) and nail involvement at baseline.

Background

- Patients with PsA who have psoriasis and/or nail involvement have greater disease severity and lower quality of life than those without.[1,2]
- BKZ, a humanized monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated sustained efficacy and safety to 3 years in patients with PsA who were biologic disease-modifying antirheumatic drug-naïve (biologic-naïve) or had prior inadequate response or intolerance to tumor necrosis factor inhibitors (TNFi-IR).[3,4]

Methods

- Post hoc analysis of BE OPTIMAL (NCT03895203; biologic-naïve) and BE COMPLETE (NCT03896581; TNFi-IR); both trials assessed subcutaneous BKZ 160 mg every 4 weeks (Q4W) in patients with PsA.
- Placebo patients switched to BKZ (PBO/BKZ) at Week 16. BE OPTIMAL reference arm (adalimumab 40 mg Q2W) patients switched to BKZ at Week 52. BE OPTIMAL Week 52 and BE COMPLETE Week 16 completers could enter BE VITAL (NCT04009499; open-label extension), where all patients received BKZ.
- Efficacy and safety data are reported for the subgroup of patients with PsA who had baseline psoriasis (≥3% body surface area) and nail involvement (modified Nail Psoriasis Severity Index >0).
- Efficacy outcomes are reported to 3 years (Week 160 in BE OPTIMAL and Week 156 in BE COMPLETE) for the BKZ Total group (PBO/BKZ and BKZ-randomized patients).
- Missing data imputed using modified non-responder (mNRI; binary), non-responder (NRI; binary) or multiple (MI; continuous) imputation. mNRI considered visits following discontinuation due to adverse events or lack of efficacy as non-response; all other missing data were imputed with MI and the response derived from imputed values.
- Safety data are reported to 3 years (Week 156) for all BKZ-treated patients (≥1 dose; including reference arm patients).

Results

- Overall, 221/712 (31.0%) biologic-naïve and 159/400 (39.8%) TNFi-IR BKZ Total group patients had baseline psoriasis and nail involvement. Of those, 181 (81.9%)/128 (80.5%) completed Week 160/156.
- Baseline characteristics are presented in **Table 1**. TNFi-IR patients had a longer disease duration and higher disease activity, compared with biologic-naïve patients.
- Efficacy responses were sustained from 1 to 3 years, with high proportions of patients demonstrating consistent and sustained improvements across all assessed PsA domains (**Figure**, **Table 2**).
- BKZ continued to be well tolerated up to 3 years (**Table 3**).
- For biologic-naïve (n=260) and TNFi-IR (n=155) patients, exposure-adjusted incidence rates (EAIR)/100 patient years (PY) for ≥1 treatment-emergent adverse event (TEAE) were 143.4 and 68.0, respectively.
- *Candida* infections (EAIR/100 PY biologic-naïve: 4.6; TNFi-IR: 1.5) were localized, none were serious and the majority were oral candidiasis. Few *Candida* infections led to study discontinuation (biologic-naïve: 2 [EAIR/100 PY: 0.3]; TNFi-IR: 0).

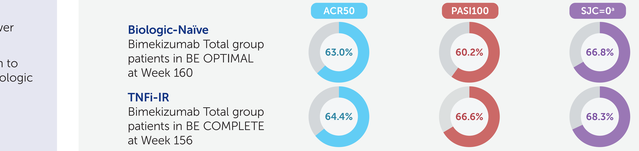
Conclusions

Patients with PsA who had baseline psoriasis and nail involvement and were treated with bimekizumab experienced sustained, high levels of treatment response across assessed domains to 3 years. Improvements were consistent regardless of prior TNFi experience. Bimekizumab was well tolerated, with a safety profile consistent with previous reports.[3–5]

Summary

Efficacy and **safety** of **bimekizumab** treatment were assessed **up to 3 years** in patients with **PsA** with **psoriasis** and **nail involvement** at baseline, who were biologic-naïve (BE OPTIMAL) or TNFi-IR (BE COMPLETE).

High levels of treatment response observed at 1 year across **joint and skin outcomes**, and in a **physician-derived measure of inflammation**, were **sustained through 3 years** with **bimekizumab treatment** (mNRI):



Bimekizumab was **well tolerated** to 3 years with **no new safety signals observed**.[3–5]

Bimekizumab treatment demonstrated **sustained clinical efficacy** up to **3 years** in patients with **PsA** who also had **psoriasis and nail involvement**.

[a] Physician-derived measure of inflammation; resolution of swollen joint count (SJC=0) was assessed in 66 joints.

Table 1 Select baseline characteristics

	BE OPTIMAL (biologic-naïve)	BE COMPLETE (TNFi-IR)
	BKZ 160 mg Q4W Total[a] n=221	BKZ 160 mg Q4W Total[a] n=159
Age, years, mean (SD)	47.3 (11.2)	49.1 (12.5)
Sex, male, n (%)	112 (50.7)	90 (56.6)
Time since PsA diagnosis, years, mean (SD)	7.5 (8.6)[b]	9.8 (9.2)[c]
Any csDMARD at baseline, n (%)	148 (67.0)	85 (53.5)
Concomitant methotrexate, n (%)	132 (59.7)	74 (46.5)
SJC (of 66 joints), mean (SD)	10.1 (7.4)	11.5 (9.5)
TJC (of 68 joints), mean (SD)	18.0 (12.4)	19.2 (14.4)
hs-CRP, mg/L, mean (SD)	12.1 (18.2)	15.1 (21.3)
≥3% BSA affected by psoriasis, n (%)		
≥3–≤10%	134 (60.6)	94 (59.1)
>10%	87 (39.4)	65 (40.9)
PASI score, mean (SD)	9.1 (7.1)	10.9 (9.4)
mNAPSI score, mean (SD)	4.4 (2.4)	4.9 (2.8)
Enthesitis (LEI >0), n (%)	67 (30.3)	52 (32.7)
LEI score,[d] mean (SD)	2.5 (1.5)	2.5 (1.4)
Dactylitis (LDI >0), n (%)	32 (14.5)	22 (13.8)
LDI score,[e] mean (SD)	62.2 (69.7)	66.4 (83.8)
HAQ-DI score, mean (SD)	0.89 (0.60)	1.06 (0.61)
FACIT-Fatigue, mean (SD)	36.8 (9.1)	35.4 (10.1)
PsAID-12 total score, mean (SD)	4.3 (1.8)	4.9 (2.0)
Pain VAS,[f] mean (SD)	58.5 (23.5)	63.3 (23.1)

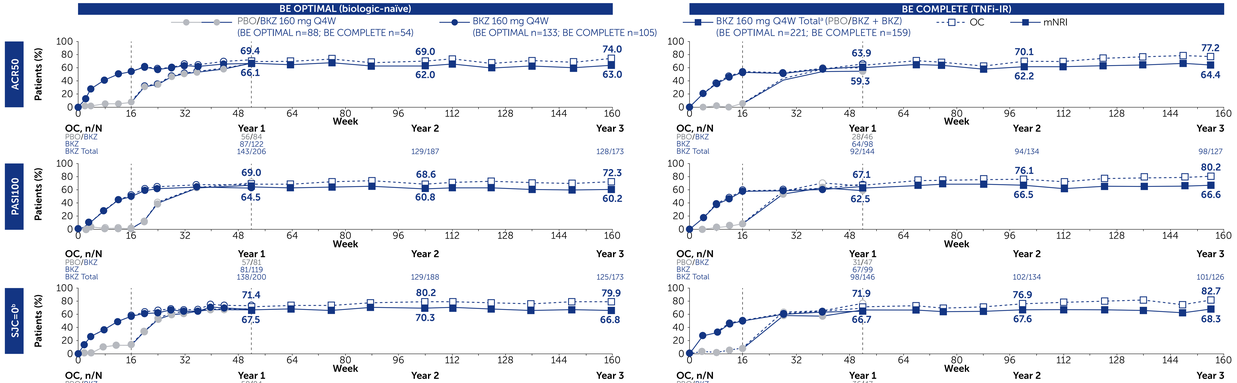
Randomized set, in patients with baseline psoriasis (≥3% BSA) and nail involvement (mNAPSI >0). **[a]** BKZ Total group includes BKZ-randomized patients and PBO patients who switched to BKZ at Week 16; **[b]** Data missing for 2 patients; **[c]** Data missing for 1 patient; **[d]** In patients with enthesitis at baseline (LEI >0); **[e]** In patients with dactylitis at baseline (LDI >0); **[f]** Pain was assessed using the Patient's Assessment of Arthritis Pain VAS, which ranges from 0 (no pain) to 100 (most severe pain).

Table 2 Additional efficacy outcomes at 3 years (mNRI, OC)

	BE OPTIMAL (biologic-naïve)		BE COMPLETE (TNFi-IR)	
	BKZ 160 mg Q4W Total[a] n=221		BKZ 160 mg Q4W Total[a] n=159	
	mNRI, %	OC, % (n/N)	mNRI, %	OC, % (n/N)
ACR20	76.8	87.3 (151/173)	78.3	91.3 (116/127)
ACR70	48.2	57.5 (100/174)	45.9	55.9 (71/127)
PASI75	83.2	93.1 (161/173)	84.4	96.8 (122/126)
PASI90	75.1	86.7 (150/173)	76.2	88.1 (111/126)
Nail psoriasis resolution (mNAPSI=0)	64.8	76.3 (132/173)	69.3	83.5 (106/127)
ACR50+PASI100	44.5	54.7 (94/172)	51.1	62.7 (79/126)
MDA[b]	57.4	67.6 (117/173)	55.7	67.7 (86/127)
TJC=0 (of 68 joints)	36.9	43.1 (75/174)	38.2	44.9 (57/127)
Enthesitis resolution (LEI=0)[c]	70.0	86.3 (44/51)	71.3	90.0 (36/40)
Dactylitis resolution (LDI=0)[d]	75.0 [NRI][e] (24/32)	96.0 (24/25)	77.3 [NRI][e] (17/22)	100 (17/17)
HAQ-DI MCID[f]	57.5	66.4 (93/140)	61.5	73.0 (81/111)
Pain VAS CfB [MI],[g] mean (SE)	−36.4 (1.9)		−39.6 (2.4)	

Randomized set, in patients with baseline psoriasis (≥3% BSA) and nail involvement (mNAPSI >0). Data imputed using mNRI and OC unless otherwise stated. Data reported to Week 160 in BE OPTIMAL and Week 156 in BE COMPLETE. **[a]** BKZ Total group includes BKZ-randomized patients and PBO patients who switched to BKZ at Week 16; **[b]** MDA response is defined as achievement of ≥5/7 of the following criteria: TJC ≤1, SJC ≤1, PASI ≤1 or BSA ≤3%, patient pain VAS ≤15, PGA-PsA VAS ≤20, HAQ-DI ≤0.5, and tender entheseal points (LEI) ≤1; **[c]** In patients with baseline enthesitis (LEI >0); BE OPTIMAL n=67; BE COMPLETE n=52; **[d]** In patients with baseline dactylitis (LDI >0; BE OPTIMAL n=32; BE COMPLETE n=22); **[e]** In cases where MI did not converge and mNRI was not available, missing data were imputed using NRI; **[f]** HAQ-DI MCID defined as decrease from baseline ≥0.35 in patients with baseline HAQ-DI ≥0.35 (BE OPTIMAL n=175; BE COMPLETE n=140); **[g]** Pain was assessed using the Patient's Assessment of Arthritis Pain VAS which ranges from 0 (no pain) to 100 (most severe pain).

Figure Study timelines and design



Randomized set, in patients with baseline psoriasis (≥3% BSA) and nail involvement (mNAPSI >0). Data reported from Year 1 (Week 52 in BE OPTIMAL and BE COMPLETE) to Year 2 (Week 104 in BE OPTIMAL and Week 100 in BE COMPLETE) and Year 3 (Week 160 in BE OPTIMAL and Week 156 in BE COMPLETE). **[a]** BKZ Total group includes BKZ-randomized patients and PBO patients who switched to BKZ at Week 16; **[b]** Resolution of swollen joint count (SJC=0) was assessed in 66 joints.

Table 3 Safety to 3 years

n (%) [EAIR/100 PY]	BE OPTIMAL (biologic-naïve)	BE COMPLETE (TNFi-IR)
	BKZ 160 mg Q4W Treated[a] (n=260) 656.0 PY	BKZ 160 mg Q4W Treated[a] (n=155) 412.7 PY
Any TEAEs	241 (92.7) [143.4]	119 (76.8) [68.0]
Serious TEAEs	37 (14.2) [6.0]	18 (11.6) [4.6]
Study discontinuation due to TEAEs	20 (7.7) [3.1]	11 (7.1) [2.7]
Drug-related TEAEs[b]	103 (39.6) [22.0]	45 (29.0) [13.7]
Severe TEAEs	26 (10.0) [4.2]	14 (9.0) [3.5]
Deaths	2 (0.8) [0.3][c]	1 (0.6) [0.2][d]
Most frequent TEAEs[e]		
SARS-CoV-2 (COVID-19) infection	58 (22.3) [9.9]	25 (16.1) [6.7]
Nasopharyngitis	52 (20.0) [9.1]	10 (6.5) [2.5]
Upper respiratory tract infection	30 (11.5) [4.9]	11 (7.1) [2.8]
Urinary tract infection	25 (9.6) [4.0]	10 (6.5) [2.6]
Oral candidiasis	22 (8.5) [3.5]	6 (3.9) [1.5]
Safety topics of interest		
Serious infections	7 (2.7) [1.1]	5 (3.2) [1.2]
Opportunistic infections	7 (2.7) [1.1]	2 (1.3) [0.5]
Active tuberculosis	0	0
Fungal infections	43 (16.5) [7.3]	13 (8.4) [3.4]
Candida infections	28 (10.8) [4.6]	6 (3.9) [1.5]
Oral candidiasis	22 (8.5) [3.5]	6 (3.9) [1.5]
Fungal infection NEC	24 (9.2) [3.9]	8 (5.2) [2.0]
Tinea infections	3 (1.2) [0.5]	1 (0.6) [0.2]
Neutropenia	10 (3.8) [1.6][f]	8 (5.2) [2.0][g]
Serious hypersensitivity reaction	0	1 (0.6) [0.2][h]
Administration/injection site reaction[i]	7 (2.7) [1.1]	4 (2.6) [1.0]
Definite or probable adjudicated IBD	2 (0.8) [0.3]	1 (0.6) [0.2]
Uveitis	1 (0.4) [0.2][j]	0
Adjudicated suicidal ideation and behaviour[k]	2 (0.8) [0.3]	0
Adjudicated MACE	3 (1.2) [0.5]	2 (1.3) [0.5]
Elevated liver enzymes[l]	33 (12.7) [5.5]	18 (11.6) [4.7]
>3x ULN ALT or AST	20 (7.7) [3.2]	6 (3.9) [1.5]
Malignancies, excluding non-melanoma skin cancer	3 (1.2) [0.5]	4 (2.6) [1.0]

Safety set, in patients with baseline psoriasis (≥3% BSA) and nail involvement (mNAPSI >0). **[a]** Safety events reported whilst receiving BKZ. For patients who switched to BKZ from PBO (Week 16) or ADA (BE OPTIMAL Week 52), includes events after switch only; **[b]** Per study investigator assessment; **[c]** One death due to traumatic shock (motorcycle accident; Week 0–52); one death due to acute myocardial infarction (Week 52–104); both deemed unrelated to treatment; **[d]** One sudden death (Week 0–52), deemed unrelated to treatment; **[e]** Most frequent adverse events are the top five adverse events based on incidence rate across both trials; **[f]** 9 neutropenia, 1 neutrophil count decreased; **[g]** 4 neutropenia, 4 neutrophil count decreased; **[h]** 1 case of dermatitis, classified as serious due to the patient needing hospitalization; **[i]** Includes the high-level term "administration site reactions NEC" and "injection site reactions"; **[j]** 1 case of indocyclitis; **[k]** There were no completed suicidal and ideation behaviour cases; **[l]** Elevated liver enzymes include the following preferred terms reported as adverse events: increased/abnormal levels of ALT, AST, blood bilirubin, gamma-glutamyl transferase, hepatic enzymes, liver function test, total bile acids, or transaminases.

ACR: American College of Rheumatology; **ACR20/50/70:** ≥20/50/70% improvement from baseline in ACR response criteria; **ACR50+PASI100:** ≥50% improvement from baseline in ACR response criteria + 100% improvement from baseline in PASI; **ADA:** adalimumab; **ALT:** alanine aminotransferase; **AST:** aspartate aminotransferase; **BKZ:** bimekizumab; **BSA:** body surface area; **CfB:** change from baseline; **csDMARD:** conventional synthetic disease-modifying antirheumatic drug; **EAIR:** exposure-adjusted incident rate; **FACIT-Fatigue:** Functional Assessment of Chronic Illness Therapy-Fatigue; **HAQ-DI:** Health Assessment Questionnaire–Disability Index; **hs-CRP:** high sensitivity C-reactive protein; **IBD:** inflammatory bowel disease; **IL:** interleukin; **LDI:** Leeds Dactylitis Index; **LEI:** Leeds Enthesitis Index; **MACE:** major adverse cardiovascular event; **MCID:** minimal clinically important difference; **MDA:** minimal disease activity; **MI:** multiple imputation; **mNAPSI:** modified Nail Psoriasis Severity Index; **mNRI:** modified non-responder imputation; **NEC:** not elsewhere classified; **NRI:** non-responder imputation; **OC:** observed case; **PASI:** Psoriasis Area and Severity Index; **PASI75/90/100:** ≥75/90/100% improvement from baseline in PASI; **PBO:** placebo; **PGA-PsA:** Patient's Global Assessment of PsA; **PsA:** psoriatic arthritis; **PsAID-12:** Psoriatic Arthritis Impact of Disease-12; **PY:** patient-years; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation; **SE:** standard error; **SJC:** swollen joint count; **SJC=0:** complete resolution of SJC; **TEAE:** treatment-emergent adverse event; **TJC:** tender joint count; **TNFi-IR:** prior inadequate response or intolerance to tumor necrosis factor inhibitors; **ULN:** upper limit of normal; **VAS:** visual analogue scale.

References: [1]Mease PJ. J Rheumatol 2021;48:520–6; [2]Walsh JA. Joint Bone Spine 2023;90:105534; [3]McInnes IB. Ann Rheum Dis 2025;84(Suppl 1):400; [4]Gossec L. Ann Rheum Dis 2025;84(Suppl 1):1337; [5]Mease PJ. Rheumatol Ther 2024;11:1363–82.
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